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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,937	06/21/2001	William Paul Bullock	031-3	4857

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,937	BULLOCK ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. The Office acknowledges receipt of Applicant's Election of 5 January 2004, electing Group I claims 1-6, drawn to a method of introducing a nucleic acid into plant cells, comprising providing a whisker cocktail, with traverse. Applicant traverses saying primarily that it is believed that a genus claimed that encompasses the modes of operations listed by the Examiner can be allowed. Thus, the five listed inventions will all be covered by a claim that covers the shaking motions and the speed and the directions that the Examiner is claiming are different modes of operation. Therefore it would be no undue burden on the Examiner to search and examine all the claims. Applicant's traversal is unpersuasive. The Group I claims 1-6 and Groups II-V claims 7-20 differ from each other in having different steps utilizing different reagents and different processes which function differently.

2. Examiner notes that claims 19 and 20 were inadvertently not assigned to groups in the restriction. This oversight is corrected here. Group IV, is drawn to claims 14-18 and 20. Group V is drawn to claim 19. The Office regrets any inconvenience this may have caused.

3. This restriction is made Final.

Status of the Claims

4. Claims 1-20 are pending. Claims 1-6, drawn to a method of introducing a nucleic acid into plant cells, comprising providing a whisker cocktail, are examined in the instant action. Claims 7-20 are withdrawn as being drawn to nonelected inventions.

Specification

5. The disclosure is objected to because of the following : In the specification, lines 17-20 p. 3, Applicant states that the closest prior art is two documents, one a US patent and one a PCT document (PCT/US99/01815). However the PCT or an equivalent is not cited in the IDS and no copy is provided.

Claim 2 is objected to as

- depending upon non-elected claims,
- depending upon greater-numbered original claims,
- being an improper multiple dependent claim.

6. Claim 2 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend upon other claims in the alternative only. See MPEP § 608.01(n). In the interest of compact prosecution, the claim will be treated on the merits. Such treatment does not relieve Applicant of the responsibility to respond to this objection.

Claim Rejections - 35 USC § 112-2

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 3 is rejected under 35 USC § 112-2 for the following reasons

In claim 3, "the seed or progeny" lacks antecedent basis.

Corrections or clarifications are required.

Claim Rejections - 35 USC § 112 Enablement

9. Following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

The breadth of the claims: Claim 1 is drawn to a method of introducing a nucleic acid into plant cells of any species and from any tissue, comprising providing a whiskers cocktail comprising (i) at least one cell, (ii) a multiplicity of whiskers and (iii) at least one nucleic acid of any type and topology, and subject said whiskers cocktail to a shaking motion of a multitude of speeds bounded only by the upper limit of less than 2100 cycles per minute, for an unspecified duration, so as to create collisions between said whiskers and said plant cells whereby said nucleic acid is introduced into said plant cells in a medium of any osmolarity. Additional claims are drawn to this method wherein the cycles per minute are less than 1000, and where cycles per minute are approximately 768. Other claims are drawn to regenerating at least one cell of any species and from any tissue of claim 1 into a plant comprising said nucleic acid . Other claims are drawn to a whiskers mediated method of transforming plant cells, comprising (a) providing a whiskers cocktail of any species and from any tissue, comprising: cells, a multiplicity of whiskers and DNA, (b) contacting said cocktail in at least one vessel adapted to be shaken, wherein said vessel is capable of retaining at least 16 ml of said cells; (c); and placing at least one of such vessels holding the cocktail in means for shaking the cocktail, and , (d) shaking with such shaking means at least one of such vessel wherein said DNA is capable of being inserted into at least one of said cells whereby forming a whiskers mediated transformed plant cell.

Lack of Guidance and unpredictability: Whiskers mediated plant cell transformation is unpredictable. A number of factors influence DNA delivery in

the whiskers method: Mixing time, cell suspension type and age, osmolarity of medium, DNA topology, for example. See WO 94/28148 pages 4 line 34 bridging to page 5, line17; Kaeppler et. al., 1990, Plant Cell Reports, vol. 9, pages 415-418, p. 417, 1st ¶ 2nd column [IDS], and Kaeppler et. al., 1992, Theor. Appl. Genet, vol. 84, pages 560-566, p. 565, 1st full ¶ [IDS].

The state of the art is that "plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one.", (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230)

Applicant teaches whisker mediated DNA transfer as measured by transient GUS expression of soybean suspension cells, elite maize callus cells, sugar beet cells and canola cells tissue using a protocol employing a Red Devil modified paint shaker shaking a whiskers cocktail at 1000 cycles or less per minute for a time duration of 5-20 seconds in a medium of N6 osmolarity (specification pages 33-45).

In view of the breadth of the claims (any cell, any explant, any plant, any nucleic acid, any shaking duration, any shaking speed, any medium osmolarity, the nature of the invention, the unpredictability of the art, the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 4, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffee, et. al., US 5,302,523, issued 12 April 1994 (IDS).

Coffee teaches a method of introducing a nucleic acid using a "whisker cocktail" consisting of maize (BMS) suspension cell line cells (column 4, lines 39-bridging to column 5, line 8), silicon carbide ceramic fibers ("whiskers"), a CaMV35S/Gus nucleic acid , and mixing (vortexing) for 10 seconds to produce transformed maize cells (Table 2, column 5). Coffee also teaches the use of 50 ml volume vessels/tubes for mixing the cocktail (column 3, lines 50-54).

It is noted that the claims 1, 4, and 5 are drawn to a means for shaking of less than 2100 cycles per minute. However since the claim is written in open language, shaking rates of more than 2100 are encompassed. When the means for shaking is turned on until it comes to speed, the cocktail is subject to a continuum of frequencies of cycles per minute, which include both 1000 and 768 cycles per minute.

Accordingly, Coffee anticipates the claimed invention.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Frame et. al., The Plant Journal, 1994, Vol. 6, No. 6, pages 941-948 (IDS).

Frame et. al. teach the production by the claimed method of fertile transgenic maize plants, and R2 homozygous progeny of same (Table 2, page 945). Frame et. al. teach the use of finger tapping, clearly at a shaking motion of less than 768 cycles per minute, which resulted in DNA transfer (see p. 942, column 1, top ¶).

Accordingly Frame et. al. anticipate the claimed invention.

Remarks

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
April 19, 2004

Amy Nelson
for David Fox

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